ORIGINAL ARTICLE

GESTATIONAL SYPHILIS: DEVELOPMENT AND VALIDATION OF AN INSTRUMENT FOR THE EVALUATION OF CLINICAL NURSING PRACTICE

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ABSTRACT

Objective: to develop and validate a data collection instrument for the evaluation of the clinical practice of nursing to pregnant women with diagnosis of syphilis in primary health care. **Method:** methodological study of instrument construction and validation. The initial version (40 items) was developed based on national and international protocols and the Donabedian's reference. The validation was performed by the Delphi Technique (two rounds) with seven judges. We used the Content Validity Index (≥0.80) and the Binomial Test (p<0.05). A pre-test was applied to 15 nurses from Primary Health Care. **Results:** version 2 (48 items) was validated by the judges, reaching a global Content Validity Index of 0.98. The Binomial Test confirmed the statistical agreement (p<0.05) for the maintained items. The pre-test resulted in version 3 (final, 48 items) in which clarity adjustments were made, demonstrating semantic adequacy. **Conclusion:** the study produced an instrument with validity of content, suitable to evaluate the nursing practice in assisting pregnant women with syphilis. The instrument is a robust tool to subsidize quality management and permanent education in primary health care, which may contribute to the elimination of congenital syphilis.

Keywords: Pregnant women. Primary health care. Syphilis. Validation study. Nursing care.

INTRODUCTION

The increasing incidence of syphilis represents a significant global public health problem. World Health Organization (WHO) estimates for 2020 indicate 7.1 million new infections per year in adults aged 15 to 49 years. The impact on maternal and child health is particularly alarming, the global rate of Congenital Syphilis (CS), resulting from vertical transmission, showed an increase in the period from 2016 to 2022, reaching 523 cases per 100,000 live births. This index exceeds by more than 2.5 times the target of 200 cases per 100,000 live births set for 2025[1].

However, this problem is not restricted to low- and middle-income countries. The Centers for Disease Control and Prevention (CDC) report, published in 2024, showed an 80.0% increase in total cases of syphilis in the United States of America (USA) between 2018 and 2022. In the same country, the increase of CS cases was even more significant, reaching 937.0% in the last decade (2012-2022). The CDC describes this scenario as an "epidemic of sexually transmitted infections (STIs)", highlighting syphilis in particular as an alarming growth threat[2].

In Brazil, there is a growing curve of cases of

gestational syphilis (GS) and CS. In 2024, 89,724 cases of GS and 24,443 cases of CS (9.6 cases/1,000 live births) were reported in the country. Thus, Brazil is far away from the global target set by the WHO of a maximum of 0.5 cases of CS per thousand live births by 2030[1,3,4].

However, preventing vertical transmission of syphilis is one of the priorities of the Brazilian Ministry of Health (MH). The country has concentrated efforts on actions of surveillance, prevention and control of vertical transmission of the Human Immunodeficiency Virus (HIV) and syphilis, aligned with the WHO Global Health Sector Strategy HIV and STI and with the sustainable development goals (SDGs) of the 2030 Agenda to eliminate vertical transmission[1,5].

Thus, through the CS elimination program, the Brazilian MH stipulates strict process indicators for certification of vertical transmission elimination. These include, notably, a minimum coverage of ≥95.0% of pregnant women with at least one test for syphilis in prenatal care and ≥95.0% of adequate treatment for those diagnosed[6].

The observance of these process goals highlights the role played by nurses in Primary Health Care (PHC) under the Family Health Strategy (FHS). This professional is directly responsible for the implementation of these actions, from the early capture of the pregnant woman, diagnostic request, to the administration and follow-up of treatment[7].

However, this persistence of the disease suggests that critical failures do not reside in biomedical technology, but in the operationalization of care processes. There is a fundamental gap in the knowledge about how this assistance is being effectively provided and which specific barriers (of knowledge, process or structure) are preventing the success of treatment and the interruption of vertical transmission[8].

Therefore, it is necessary to understand why a disease such as syphilis, which has affordable and low-cost diagnosis and treatment, still remains a serious global public health problem[9].

To overcome this gap, it is imperative to systematically evaluate clinical practice. However, there is a lack of validated instruments, specific to the Brazilian context, that measure compliance and clinical nursing practice against GS protocols in PHC. Without a robust diagnostic tool of care practice, managers and researchers cannot accurately identify the weaknesses of the service to then propose assertive educational or structural interventions.

Thus, this scenario raises the following guiding question: How to identify, in a valid way, the assistance provided by the PHC nurse to the pregnant woman with diagnosis of syphilis? Given the above, the objective of this study is to develop and validate a data collection instrument for the evaluation of the clinical practice of nursing to pregnant women with diagnosis of syphilis in primary health care.

METHOD

This is a methodological development study[10], with quantitative approach, designed for the construction and validation of a data collection instrument (questionnaire) intended to evaluate the clinical practice of nursing to pregnant women with syphilis in PHC.

The methodological path was based on the Delphi Technique[11] and the referential of Polit & Beck[10] and followed three central steps: (1) Construction of the Data Collection Instrument; (2) Content Validation (Delphi Technique); and (3) Pre-/Pilot Test (appearance and semantic validation).

Step 1: Construction of the Data Collection Instrument

The construction of the preliminary version of the instrument was based on the following steps:

- documentary analysis of national and international clinical protocols (MH and World Health Organization - WHO) on the management of GS. The theoretical framework was based on the Donabedian's Health Quality Assessment model (Structure, Process and Outcome), focusing on the Process dimension[12].

- definition of the objective of the instrument - collect data that allows "the evaluation of the compliance of the assistance provided by PHC nurses to pregnant women with a diagnosis of syphilis, compared to the current protocols".

- definition of the target population - "nurses working in FHS".

- creation of the items of the instrument based on the conceptual dimensions distributed in three sections: (I) Characterization of the Nurse, with sociodemographic and professional data; (II) Prenatal Assistance to Pregnant Women with

Diagnosis of Syphilis, addressing diagnosis, definition of syphilis stage, treatment, follow-up and treatment of the partner, post-treatment follow-up of the pregnant woman and the exposed newborn or with CS diagnosis; (III) Opinion on Facilitators and Barriers in the Assistance to Pregnant Women with Diagnosis of Syphilis for Prevention of Congenital Syphilis.

Step 2: Content Validation (Delphi Technique)

The Delphi Technique was used for validation, characterized by an anonymous consensus process obtained from a group of experts (judges) through successive rounds. This method allows the controlled interaction of opinions through feedback from the responses aggregated to each round, focusing on the technical-scientific content[10,13]. Although consensus levels vary in the literature, an 80.0% cut-off criterion was defined a priori to consider the appropriate instrument[14,15].

The response scale adopted for the evaluation of the process items was the three-point Likert type (1=Disagreement; 2=Partially agree; 3=Strongly agree). In content validation, scales with three or four points instead of five points are more indicated by eliminating the "neutral" ambiguous point[10].

The selection of experts (judges) was intentional, using the Lattes Platform as a primary search tool. To ensure the validity of content, the sample sought to contemplate specialists with diversity of performance (teaching, research and assistance) and national geographic distribution. The inclusion criteria for the definition of expertise were: to be a specialist, master and/or doctor in nursing or collective health; have at least five years' experience (teaching or care) in PHC or maternal-area children; and/or be a teacher and researcher linked to public or private institutions with relevant bibliographic production in the area of maternal and child health or STI in the last five years. There were no exclusion criteria because they were previously selected by their expertise in the area of study.

The search strategy on the platform was operationalized using the following descriptors in the fields "Subject" or "Line of Research": ["Gestational Syphilis" AND "Nursing" AND "Primary Health Care"].

The contact with the judges occurred individually, through institutional or personal e-mail, consisting of an invitation with instructions on the study, the instrument and the Informed Consent Form (ICF), which was signed and returned, also by e-mail.

The deadline of seven days was stipulated for the return, being made reminder by e-mail 48 hours before the expiration of the deadline. Two judges did not respond and requested an extension of the deadline by another seven days. The request was accepted and both submitted the assessment on the agreed date. The process was repeated in the subsequent round.

The judges evaluated each item of the instrument considering the form of presentation of the questions, content addressed and the ability to achieve the proposed objectives, that is, to carry out a situational diagnosis of the assistance provided by the PHC nurse to pregnant women diagnosed with syphilis. When the partially agree option is chosen (2), they should suggest which updates would be necessary to meet the objectives[11,16].

The instrument circulated among the judges until the level of agreement was reached, and for this, two rounds were necessary. This process took place in the period from August 11 to October 7, 2021.

Step 3: Pre-test (appearance and semantic validation)

After the consensus of the judges and the consolidation of the final version of the instrument, the pre-test/pilot was carried out. This step aimed to evaluate the clarity of appearance and semantics, legibility, average time of completion and adequacy of the response scale with the target population. The instrument was applied to a convenience sample of 15 PHC nurses from different cities in the states of São Paulo and Minas Gerais, who had a profile similar to that of the final sample, but did not participate in the content validation stage. After signing the ICF and responding to the data collection instrument, these nurses were asked about the understanding of the issues and difficulties encountered in answering them.

In this step, adjustments were made to eliminate ambiguities or difficulties of interpretation.

Data analysis

The content validation analysis (Step 2) was

performed by calculating the Content Validity Index (CVI) per item (I-CVI) and for the total instrument (S-CVI). The I-CVI was operationalized as the proportion of judges who assigned the maximum score ('Agree Totally' - score 3) to a given item. The S-CVI was determined by the mean of the I-CVI of all evaluated items (S-CVI/Avg). We adopted as a cut-off criterion for consensus an IVC $\geq$0.80[10]. To statistically test the significance of agreement, we used the Binomial Test. This test assessed whether the proportion of 'I agree totally' responses in each item was significantly higher than the criterion of 0.80 ($p<0.05$). The analyses were conducted in the software Statistical Package for Social Science (SPSS), version 24.0. The data from the pre-test (Step 3) were analyzed descriptively.

This research was approved by the Research Ethics Committee of the Federal University of Alfenas, opinion: n. 4.893.857.

RESULTS

The version of the instrument initially built - Version 1 (V1) contained 40 items (structural questions), which were derived from a checklist of sensitive indicators, developed by researchers after documentary analysis of current protocols. The structure of V1 comprised three sections: Characterization of the Nurse (seven items);

Evaluation of Prenatal Care to Pregnant Women with Syphilis (18 items), detailing diagnosis, treatment (pregnant woman/partner) and follow-up; and Opinion on Facilitators and Barriers in the Assistance to Pregnant Women with Syphilis Diagnosis for Prevention of Congenital Syphilis (15 items).

In the consultation to the Lattes Platform, 15 professionals with experience in the area were identified and, of these, 13 met the inclusion criteria established for the composition of the judges participating in the *Content Validation Stage by the Delphi Technique*.

The 13 professionals were invited to participate in the study via e-mail. Of these, seven accepted to participate and composed the final sample (53.8% adherence rate), a number considered appropriate for content analysis[14]. The final sample was composed of experts from four different institutions, representing two of the five regions of the country, ensuring heterogeneity of perspectives. The sample profile (Table 1) revealed a predominance of females, aged between 40 and 50 years. Most of the specialists had a doctor's degree, worked as a professor at a public university and reported experience in women's health or collective health between 11 and 20 years.

Table 1. Characterization of the experts (judges). Alfenas, Minas Gerais. 2022

Variables	Experts	
	(n=7)	(%)
Sex		
Female	6	85.7
Male	1	14.2
Age group		
20 – 30 years	1	14.2
31 – 40 years	2	28.5
41 – 50 years	4	57.1
Education		
Lato sensu - specialization	1	14.2
Stricto sensu - MSc	2	28.5
Stricto sensu - PhD	4	57.1
Professional Work		
Primary Health Care Professional	3	42.8
Professor (Government University)	4	57.1
Time working in the area of women's health or collective health		
5 – 10 years	2	28.5
11 – 20 years	4	57.1
21 – 30 years	1	14.2

Source: the authors (2022).

Evaluated the agreement between the judges, 15 items obtained CVI ≥0.80 and p-value less than 0.05. The lowest CVI observed was in relation to question 10 of section II - Prenatal Care for Pregnant Women with Syphilis Diagnosis, which obtained CVI=0.29. The first round obtained 37.5% of agreement among the judges.

All items with CVI below 0.80 were reviewed according to the judges' suggestions. Among the suggestions presented were: addition of eight questions to better detail the prenatal care offered, addition of answer options for some items, aiming to better elucidate about the knowledge of the nurse and better description of the items to broaden the understanding of the participant in relation to what was expected to know.

Table 2 shows that judges three and six strongly agreed (3) with all the questions and that the dissenting assessment (1) was not applied to any of the questions. This was probably due to the fidelity in the elaboration of the questions, to the guidelines for managing syphilis in pregnant women by PHC nurses.

Table 2. Content Validation Index and Inter-rater Agreement (first round). Alfenas, Minas Gerais. 2022

Items	Exp 1	Exp 2	Exp 3	Exp 4	Exp 5	Exp 6	Exp 7	IVC	p-value
Section I - Characterization of the Nurse									
1	3	2	3	3	3	3	2	0.71	0.06
2	3	3	3	3	3	3	2	0.86	**0.01**
3	3	2	3	2	2	3	2	0.43	0.50
4	2	3	3	3	2	3	3	0.71	0.06
5	2	2	3	2	2	3	3	0.43	0.50
6	2	3	3	3	2	3	3	0.71	0.06
7	3	3	3	3	2	3	2	0.71	0.06
Section II - Prenatal Care for Pregnant Women Diagnosed with Syphilis									
8	2	3	3	3	2	3	3	0.71	0.06
9	2	3	3	3	2	3	3	0.71	0.06
10	2	2	3	2	2	3	2	0.29	0.77
11	3	3	3	3	3	3	2	0.86	**0.01**
12	3	3	3	3	3	3	2	0.86	**0.01**
13	2	3	3	3	2	3	3	0.71	0.06
14	3	3	3	3	2	3	2	0.71	0.06
15	2	2	3	3	2	3	2	0.43	0.50
16	2	2	3	3	2	3	2	0.43	0.50
17	2	2	3	3	2	3	2	0.43	0.50
18	2	2	3	3	2	3	2	0.43	0.50
19	3	3	3	3	2	3	3	0.86	**0.01**
20	2	3	3	3	3	3	3	0.86	**0.01**
21	2	3	3	3	2	3	3	0.71	0.06
22	3	3	3	3	3	3	2	0.86	**0.01**
23	3	2	3	2	2	3	3	0.57	0.23
24	3	3	3	3	3	3	2	0.86	**0.01**
25	2	3	3	2	3	3	3	0.71	0.06
Section III - Opinion on Facilitators and Barriers in the Care of Pregnant Women Diagnosed with Syphilis for the Prevention of Congenital Syphilis									
26	3	3	3	3	3	3	2	0.86	**0.01**
27	3	3	3	3	3	3	2	0.86	**0.01**
28	3	3	3	2	2	3	3	0.71	0.06
29	2	3	3	3	3	3	3	0.86	**0.01**
30	3	3	3	2	3	3	3	0.86	**0.01**
31	2	3	3	3	2	3	2	0.57	0.23
32	2	3	3	3	2	3	2	0.57	0.23
33	3	3	3	3	2	3	2	0.71	0.06
34	3	3	3	3	3	3	2	0.86	**0.01**
35	3	3	3	3	3	3	2	0.86	**0.01**

36	2	3	3	3	2	3	2	0.57	0.23
37	3	3	3	3	2	3	3	0.86	**0.01**
38	2	3	3	3	2	3	2	0.57	0.06
39	3	3	3	3	2	3	2	0.71	0.06
40	3	3	3	3	3	3	2	0.86	**0.01**
Total Items IVC								**0.37**	

Legend: Exp: Expert. IVC: Item Validity Index. p-value: Statistical Significance by Binomial Test. 1: Disagree. 2: Partially Agree. 3: Strongly Agree.
Source: the authors (2022).

In the second round of evaluation, after the adaptation of the instrument with the judges' suggestions, all questions obtained CVI ≥0.80 and p-value less than 0.05. Minor suggestions to improve the description were presented in nine items of the instrument, and all of them were accepted.

Table 3 shows that judges 1, 2, 3 and 6 Strongly Agreed with all items evaluated. It is noteworthy that the S-CVI was 1.0, and demonstrated that all items of the instrument were positively evaluated by all judges involved in content validation, considering them adequate and relevant to measure what they propose[10].

Table 3. Content Validation Index and Inter-rater Agreement (second round). Alfenas, Minas Gerais. 2022

Items	Exp 1	Exp 2	Exp 3	Exp 4	Exp 5	Exp 6	Exp 7	IVC	p-value
Section I - Characterization of the Nurse									
1	3	3	3	3	3	3	3	1.00	0.00
2	3	3	3	3	3	3	2	0.86	0.01
3	3	3	3	2	3	3	3	0.86	0.01
4	3	3	3	3	3	3	3	1.00	0.00
5	3	3	3	3	3	3	3	1.00	0.00
6	3	3	3	3	3	3	3	1.00	0.00
7	3	3	3	3	3	3	3	1.00	0.00
Section II - Prenatal Care for Pregnant Women Diagnosed with Syphilis									
8	3	3	3	3	3	3	3	1.00	0.00
9	3	3	3	3	3	3	3	1.00	0.00
10	3	3	3	3	3	3	3	1.00	0.00
11	3	3	3	3	3	3	3	1.00	0.00
12	3	3	3	3	3	3	3	1.00	0.00
13	3	3	3	2	3	3	3	0.86	0.01
14	3	3	3	2	3	3	3	0.86	0.01
15	3	3	3	3	3	3	3	1.00	0.00
16	3	3	3	3	3	3	3	1.00	0.00
17	3	3	3	3	3	3	3	1.00	0.00
18	3	3	3	3	3	3	3	1.00	0.00
19	3	3	3	3	3	3	3	1.00	0.00
20	3	3	3	3	3	3	3	1.00	0.00
21	3	3	3	3	3	3	3	1.00	0.00
22	3	3	3	3	3	3	3	1.00	0.00
23	3	3	3	3	3	3	3	1.00	0.00
24	3	3	3	3	3	3	3	1.00	0.00
25	3	3	3	3	3	3	3	1.00	0.00
26	3	3	3	3	3	3	3	1.00	0.00
27	3	3	3	3	3	3	3	1.00	0.00
28	3	3	3	3	3	3	3	1.00	0.00
29	3	3	3	3	2	3	3	0.86	0.01
30	3	3	3	3	3	3	3	1.00	0.00

31	3	3	3	3	2	3	3	0.86	0.01
32	3	3	3	3	3	3	3	1.00	0.00

Section III - Opinion on Facilitators and Barriers in the Care of Pregnant Women Diagnosed with Syphilis for the Prevention of Congenital Syphilis

33	3	3	3	3	3	3	3	1.00	0.00
34	3	3	3	3	3	3	3	1.00	0.00
35	3	3	3	3	3	3	3	1.00	0.00
36	3	3	3	3	3	3	3	1.00	0.00
37	3	3	3	3	3	3	3	1.00	0.00
38	3	3	3	3	2	3	3	0.86	0.01
39	3	3	3	3	2	3	3	0.86	0.01
40	3	3	3	3	2	3	3	0.86	0.01
41	3	3	3	3	3	3	3	1.00	0.00
42	3	3	3	3	3	3	3	1.00	0.00
43	3	3	3	3	3	3	3	1.00	0.00
44	3	3	3	3	3	3	3	1.00	0.00
45	3	3	3	3	3	3	3	1.00	0.00
46	3	3	3	3	3	3	3	1.00	0.00
47	3	3	3	3	3	3	3	1.00	0.00
48	3	3	3	3	3	3	3	1.00	0.00
Total Items IVC								**1.0**	

Legend: Exp: Expert. IVC: Item Validity Index. p-value: Statistical Significance by Binomial Test. 1: Disagree. 2: Partially Agree. 3: Strongly Agree.
Source: the authors (2022).

Version 2 (V2) of the instrument contains 48 items, seven (14.5%) referring to the Nurse's Characterization (semi-structured questions), 25 (52.0%) address the Prenatal Care for Pregnant Women with Syphilis Diagnosis - all questions are multiple choice, and 16 (33.3%) the Opinion on Facilitators and Barriers in Assistance to Pregnant Women with Syphilis Diagnosis for Prevention of Congenital Syphilis - all closed.

The results of the pre-test for validation of appearance and semantics with 15 nurses working in PHC and with a profile similar to that of the final sample, but who did not participate in the content validation step, indicated a positive overall evaluation. The suggestions received were systematically analyzed by the researchers, being fully or partially accepted for the consolidation of the final version of the instrument. Chart 1 presents the synthesis of the main feedbacks and the deliberations of the researchers.

Participants	Regarding the understanding of the instrument	Suggestions
	Your research was very interesting and relevant, given the syphilis outbreak we are experiencing. I found the instrument well-designed and explanatory, and easy to understand; however, I couldn't be of much help with the treatment prescription section because the municipality where I work doesn't have a protocol for prescribing medication. Congratulations on the initiative and the relevance of the work.	NSA
2	*Very practical and easy to understand.*	NSA
3	*It was easy to understand, straightforward! In fact, it was even good for remembering and reflecting on some things. Which, I believe, is one of its purposes.*	NSA
4, 5 and 15	No suggestions	NSA
6	*I thought it was good. I was just a little confused about the facilitating factors and barriers: whether the service was easily offered to the patient or if there*	Changed

	were barriers to accessing it. I think that part needs to be clearer.	
7	*In the part about the partner's treatment, I was a little confused, but after rereading it, I understood. It's very good because when the pregnant woman has a positive pregnancy test and a negative VDRL test, we consider it a scar, and the partner with negative tests is also considered a scar.*	NSA
8	*It was easy to understand.*	NSA
9	*I had difficulty understanding the questions regarding the penicillin administration protocol.*	Changed
10	*It was easy to understand, although I was a little confused about the facilitators and barriers, and whether I should answer generally or specifically about my individual case.*	Changed
11	*I had to look up the questions to answer them, because we follow protocol and therefore don't always remember.*	NSA
12	*The difficulty was related to the generation. Now, regarding those questions about facilitators and barriers, I was very unsure. I don't know if the answer was about whether having them would be good or bad; I answered that everything was a facilitator because I understood that having them would make things easier. But I think you wanted to know if this existed here at work or not? Oh, I don't know, I was very unsure.*	Changed
13	*I found it very interesting, but perhaps it could be more condensed. My colleagues are all rushing around, overwhelmed; maybe that part about facilitators and barriers could be removed or reduced. Making the instrument shorter and more compact would be easier.*	Not changed
14	*It was very clear, easy to understand.*	NSA

Chart 1. Key feedback from the pre-test and suggestions adopted. Alfenas, Minas Gerais. 2022
Source: the authors (2022).

The pre-test analysis resulted in the instrument version 3 (V3) (Chart 2). The number of items was preserved, and only semantic adjustments were implemented to ensure the interpretability of the questions, as pointed out by the nurses.

PART I - Characterization of the Nurse
1) Sex:
2) Age (years):
3) Year of graduation in Nursing:
4) Total time spent working in a Family Health Team:
5) Do you hold a specialization and/or master's and/or doctoral degree? If so, which one(s)? From which institution(s)?
6) Have you completed any refresher or advanced training on syphilis in the last five years?
7) Do you have the training/certification to perform rapid syphilis testing?
PART II - Prenatal Care for Pregnant Women Diagnosed with Syphilis
8) Is there a municipal protocol for nurses to provide care to pregnant women diagnosed with syphilis?
9) If there is no municipal protocol, your care is based on:
10) Is the nurse responsible for the initial prenatal care in the service where you work?
11) Does the nurse conduct follow-up prenatal consultations at the service where you work?
12) Do you perform rapid syphilis testing during the first prenatal visit?
13) Do you perform rapid syphilis testing in the second and third trimesters of pregnancy?
14) Who is responsible for mandatory reporting in confirmed cases of syphilis?
15) When do you consider a serological scar to be present in a reactive rapid syphilis test?
16) If a pregnant woman's rapid test is positive for syphilis and she has no documented prior treatment, what is the correct course of action?
17) Is the partner tested and treated at the same time as the pregnant woman?
18) Does the nurse provide prenatal care for the partner at the service where you work?
19) Is benzathine benzylpenicillin administered in your unit even without the presence of a doctor?

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20) What treatment protocol do you recommend for a pregnant woman with primary lesions and a reactive rapid test?

21) What treatment protocol do you recommend for a pregnant woman with secondary lesions who has a reactive rapid test?

22) What treatment protocol do you recommend for an asymptomatic pregnant woman with a history of primary and/or secondary lesions less than a year ago and who has a reactive rapid test?

23) What treatment protocol do you recommend for an asymptomatic pregnant woman with a history of primary and/or secondary lesions more than a year ago and who has a reactive rapid test?

24) What treatment protocol do you recommend for a pregnant woman with syphilitic lesions in organs and tissues and who has a reactive rapid test?

25) What treatment protocol do you recommend for an asymptomatic pregnant woman without a history of primary and/or secondary lesions and who has a reactive rapid test?

26) Is there active outreach to pregnant women diagnosed with syphilis who miss appointments to ensure treatment is not interrupted?

27) If a pregnant woman is undergoing treatment with a prescription of 7,200 IU of benzathine benzylpenicillin in three doses of 2,400 IU at seven-day intervals, and misses one of the doses, what is your course of action?

28) Is a pregnant woman diagnosed with syphilis asked to undergo a monthly VDRL test until the end of her pregnancy to monitor cure and treatment effectiveness?

29) Are cases of congenital syphilis discussed in the Maternal, Fetal, and Infant Mortality Investigation Committee of the municipality where you work?

30) Are you currently monitoring any pregnant women who test positive for syphilis?

31) During your experience in prenatal care, have there been any cases of congenital syphilis?

32) Are children with or exposed to syphilis monitored with a specific protocol for two years in the unit where you work?

PART III - Opinion on Facilitators and Barriers in Assisting Pregnant Women Diagnosed with Syphilis for the Prevention of Congenital Syphilis

Select the FACILITATOR option for items that you consider facilitators in your care, and the BARRIER option for items that hinder or prevent this nursing care for pregnant women with syphilis in primary health care, according to your opinion:

33) Availability of rapid tests for syphilis:

34) Availability of benzathine benzylpenicillin in the unit:

35) Easy and quick access to the VDRL test through the UHS for diagnostic confirmation and cure monitoring:

36) Nurse's knowledge of the management of pregnant women with syphilis:

37) Access to courses and training on syphilis care protocols:

38) Referral from UHS hospital units for cases of exposure to syphilis or diagnosis of congenital syphilis:

39) Referral from UHS hospital units for cases of abortion or stillbirth as a consequence of congenital syphilis:

40) Referral from UHS hospital units for cases of care for pregnant women with syphilis:

41) Support from the municipal Epidemiological Surveillance for follow-up and resolution of reported cases of gestational syphilis:

42) Adherence of the pregnant woman to the proposed treatment:

43) Participation and collaboration of the partner:

44) Complete team (doctor, nurse, nursing technician and community health agents) in the unit of operation:

45) Sufficient time for comprehensive prenatal care for the pregnant woman:

46) Autonomy of the nurse in assisting pregnant women with syphilis:

47) Collaboration of the FHt in the care of pregnant women with syphilis:

48) Please report something you consider important regarding prenatal care for pregnant women diagnosed with syphilis at the health unit where you work.

Chart 2. Questions from the Data Collection Instrument after content validation and pre-testing. Alfenas, MG. 2022

Source: the authors (2022). IU: International Units. VDRL: Venereal Disease Research Laboratory. UHS: Unified Health System. FHt: Family Health Team

DISCUSSION

The development and validation of this methodological data collection instrument represent an advance beyond academia, as it can allow to respond to the care gap that maintains high rates of CS in the country. The main utility of this instrument in the practice of PHC lies in its potential as a diagnostic and quality management

tool. Its systematic application allows local managers and nursing coordinators to accurately identify the procedural weaknesses that today may be invisible.

This approach is methodologically analogous to the successful experience of incorporating the Primary Care Assessment Tool (PCATool), which consolidated the use of "solid scientific methodology" for monitoring the general attributes of PHC at national level. Similarly, the instrument now validated applies this logic to the micro-assistance level, in which it allows "disaggregate" the evaluation, leaving the impact indicator (the SC rate) for the diagnosis of the process (the why of the rate), establishing a "baseline" for comparisons between teams and the assertive direction of permanent education policies[17].

Studies highlight the importance of well-defined protocols and the need for continuous training of professionals for correct management of syphilis[18]. In the national scenario, research points to the persistence of failures in prenatal care and the need for more effective strategies to eliminate vertical transmission of syphilis[19].

Therefore, this instrument may become a useful tool for the evaluation of clinical practice of nursing to pregnant women with syphilis in PHC, especially by nurses. Its practical application can identify critical points in the care of pregnant women with syphilis, allowing targeted interventions and improvements in care protocols.

The instrument had an adequate validation of content and agreement between the judges and target population, as observed in the results of Steps 2 and 3.

A study conducted in Brazil with PHC nurses on the management of syphilis concluded that despite having received training, many had difficulties in responding to the survey, showing that care needs to be improved, and suggest continuing education as a strategy[20].

The use of this instrument has the potential to enable systematic monitoring of the care provided to pregnant women with syphilis in PHC, helping to identify gaps in clinical practice. More importantly, it can act as a diagnostic tool that, by identifying the procedural and knowledge weaknesses of nurses, allows assertively directing future training. This study therefore contributes to filling a relevant methodological gap, since the literature lacks validated instruments that monthly

care from the perspective of the health team, focusing on the individual difficulties of the professional, as opposed to existing tools aimed at user education[21].

The pre-test step (Step 3), in turn, revealed findings beyond simple validation of appearance and semantics. Although the instrument was considered clear and easy to apply, the confusion reported by the target nurses in section III (Facilitators and Barriers) is a relevant result. It suggests the real difficulty that the tip professional faces in dissociating structural (systemic) barriers from procedural barriers (individual or team), corroborating the complexity of the phenomenon. In addition, the feedback that the instrument induced reflection on the practice itself signals its latent potential as a professional self-assessment tool.

Nevertheless, difficulties in its application are anticipated, notably the resistance due to the overload of nurses' work or the bias of social desirability, which can mask real practices. Having overcome these challenges, the implications for public policies are evident, the data generated by this instrument are robust subsidies for the assertive planning of permanent education actions, focused on the specific gaps detected, and for the reorganization of aiming, ultimately, the effective elimination of vertical transmission.

Finally, the limitations of this study should be recognized. The sample of specialists (judges), although numerically suitable for the Delphi Technique and CVI calculation, was intentional and concentrated in professionals from public universities, which may introduce an academic bias. Future research is essential to complete the psychometric validation of the instrument, including the analysis of its reliability (test-retest and internal consistency, via Cronbach's alpha) and construct validation (factorial analysis).

Despite these limitations, the study provides a valid instrument in its appearance and content, ready for application. It is suggested that future researches use it in different contexts (large urban centers and rural areas) and, in a more robust way, correlate its findings (process scores) with the impact indicators (SC rates), as measured by this instrument, is in fact associated with the reduction of vertical transmission.

CONCLUSION

This methodological study achieved its objective by developing and validating the content of an unprecedented instrument for the evaluation of nursing practice in the management of gestational syphilis in PHC.

The main contribution of this study transcends validation itself; it delivers to academia and, above all, to PHC management, a diagnostic tool capable of filling an essential methodological gap. The instrument allows the syphilis paradox to be objectively measured, shifting the focus of the failure of the result indicators (SC rates) to the measurement of the care process that originates them.

It is concluded that the instrument is a valid tool in its content, with potential for immediate application to subsidize the planning of permanent education actions and the reorganization of service flows. It is recommended its use in different contexts of PHC for the diagnosis of the practice and, as a scientific advance, the continuity of its psychometric validation, with measurement of reliability and construct validity.

SÍFILIS GESTACIONAL: DESENVOLVIMENTO E VALIDAÇÃO DE UM INSTRUMENTO PARA AVALIAÇÃO DA PRÁTICA CLÍNICA DE ENFERMAGEM

RESUMO

Objetivo: desenvolver e validar um instrumento de coleta de dados para a avaliação da prática clínica de enfermagem às gestantes com diagnóstico de sífilis na Atenção Primária à Saúde. **Método**: estudo metodológico de construção e validação de instrumento. A versão inicial (40 itens) foi elaborada com base em protocolos nacionais e internacionais e no referencial de Donabedian. A validação foi realizada pela Técnica Delphi (duas rodadas) com sete juízes. Utilizou-se o Índice de Validade de Conteúdo (≥0,80) e o Teste Binomial (p<0,05). Um pré-teste foi aplicado a 15 enfermeiros da Atenção Primária à Saúde. **Resultados**: a versão 2 (48 itens) foi validada pelos juízes, alcançando um Índice de Validade de Conteúdo global de 0,98. O Teste Binomial confirmou a concordância estatística (p< 0,05) para os itens mantidos. O pré-teste resultou na versão 3 (final, 48 itens) na qual foram realizados ajustes de clareza, demonstrando adequação semântica. **Conclusão**: o estudo produziu um instrumento com validade de conteúdo, apto para avaliar a prática assistencial do enfermeiro na assistência às gestantes com sífilis. O instrumento é uma ferramenta robusta para subsidiar a gestão da qualidade e a educação permanente na Atenção Primária à Saúde, podendo contribuir para a eliminação da sífilis congênita.

Palavras-chave: Gestantes. Atenção primária à saúde. Sífilis. Estudo de validação. Cuidados de enfermagem.

SÍFILIS GESTACIONAL: DESARROLLO Y VALIDACIÓN DE UN INSTRUMENTO PARA EVALUACIÓN DE LA PRÁCTICA CLÍNICA DE ENFERMERÍA

RESUMEN

Objetivo: desarrollar y validar un instrumento de recolección de datos para la evaluación de la práctica clínica de enfermería a las gestantes con diagnóstico de sífilis en la Atención Primaria de Salud. **Método**: estudio metodológico de construcción y validación del instrumento. La versión inicial (40 ítems) fue elaborada en base a protocolos nacionales e internacionales y al referencial de Donabedian. La validación fue realizada por la Técnica Delphi (dos rondas) con siete jueces. Se utilizó el Índice de Validez del Contenido (≥0,80) y la Prueba Binomial (p<0,05). Se aplicó una prueba preliminar a 15 enfermeros de Atención Primaria de Salud. **Resultados**: la versión 2 (48 ítems) fue validada por los jueces, alcanzando un Índice de Validez de Contenido global de 0,98. La Prueba Binomial confirmó la concordancia estadística (p<0,05) para los ítems mantenidos. El pre-test resultó en la versión 3 (final, 48 ítems) en la que se realizaron ajustes de claridad, demostrando adecuación semántica. **Conclusión**: el estudio produjo un instrumento con validez de contenido, apto para evaluar la práctica asistencial del enfermero en la asistencia a las gestantes con sífilis. El instrumento es una herramienta robusta para apoyar la gestión de la calidad y la educación permanente en la Atención Primaria de Salud, pudiendo contribuir a la eliminación de la sífilis congénita.

Palabras clave: Gestantes. Atención primaria de salud. Sífilis. Estudio de validación. Cuidados de enfermería.

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